

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COPY

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BIOVAIL LABORATORIES	:	CIVIL ACTION
	:	NO. 02-CV-7119
Plaintiff	:	
	:	
vs.	:	
	:	
TORPHARM, INC.	:	Philadelphia, Pennsylvania
	:	February 10, 2004
	:	
Defendant	:	
	:	IN-CHAMBER CONFERENCE

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TRANSCRIPT OF PROCEEDINGS  
BEFORE THE HONORABLE ANITA B. BRODY  
UNITED STATES DISTRICT COURT JUDGE

APPEARANCES:

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1 (At 2:03 p.m. in chambers.)

2 DEPUTY CLERK: On the record.

3 THE COURT: All right.

4 Now, there are a couple of questions -- and we're on  
5 the record, because I just -- I had -- I scheduled this in a way  
6 -- with somebody in mind that I had thought that maybe, I would  
7 like to outline what we're going to do in the Markman hearing.

8 As I reviewed all the papers, which I did quite  
9 carefully, some other issues came up and that's the reason when  
10 you asked me, Mr. Cohen, whether you should be here, I -- I told  
11 my law clerk that I did think you should be here.

12 MR. COHEN: Yes.

13 THE COURT: So, I hate to bring you from Chicago, but  
14 sometimes, you really need to --

15 MR. COHEN: No, I -- I understand that.

16 THE COURT: -- you need to be here and I -- I don't  
17 want -- I didn't want to be constrained to ask things when I  
18 felt that there might be somebody around, who couldn't answer  
19 them.

20 MR. COHEN: Right. And -- and I understand. I was --  
21 I just wanted to find out what kind of hearing this was going to  
22 be.

23 THE COURT: I can understand that and I -- you know --  
24 I had no objection to your asking.

25 MR. COHEN: Right.

1 THE COURT: It's just that I had to -- I had to bring  
2 you in.

3 MR. COHEN: Right. That's fine.

4 THE COURT: And it may not -- you may not be needed,  
5 but I have to assume that you might be.

6 MR. COHEN: Right.

7 THE COURT: Okay. Let me talk about some of the  
8 issues that I see and what we ought to do about them.

9 You -- the defendant made quite a fuss about the  
10 collateral estoppel issue and you briefed it, really, quite  
11 extensively.

12 My recollection is that the plaintiff did not. You  
13 kind of tangentially mentioned it, am I correct about that?

14 MR. COHEN: No, we actually have -- we have a whole  
15 section devoted to it.

16 THE COURT: Okay. So, you're happy with your response  
17 -- I -- I don't know how I'm going to go, honestly.

18 MR. COHEN: Okay.

19 THE COURT: When I tell you, I don't, anyone who has  
20 been in this district knows that I'm -- sometimes, I'm too blunt  
21 -- but I -- you'll know just what I -- whether I am or I am not.

22 MR. COHEN: Okay.

23 THE COURT: I have not made a decision on that. I  
24 want to know whether the two of you are comfortable with resting  
25 on your -- your briefs -- or do you feel that you need more time

1 to -- to deal with this issue.

2 MR. SILVER: We're happy with our briefs.

3 THE COURT: Okay. Now -- and you're happy with yours?

4 MR. COHEN: We're happy with the brief and --

5 THE COURT: All right. Let me --

6 MR. COHEN: -- we'd be prepared to address --

7 THE COURT: -- let me -- okay, that's fine.

8 MR. COHEN: Right.

9 THE COURT: The couple of things you did not discuss  
10 that I have to know about, is what -- what law is applicable?  
11 In other words, what -- I know that the -- the general principle  
12 is, this has to -- it was a Florida case, wasn't it?

13 MR. SILVER: Yes.

14 THE COURT: This -- that this -- that my ruling has to  
15 be consist -- I believe it is, unless you can advise me  
16 otherwise -- that it has to have the same -- I'll call it res  
17 judicata effect -- although it's not res judicata, it's  
18 collateral estoppel as it would have been down in a Florida  
19 court. But I don't know if that means they'd looked to Florida  
20 state law on it or if there's some body of collateral estoppel  
21 law that is federal.

22 MR. COHEN: There is actually -- and I was actually --  
23 I read through the cases again, your Honor, and I was thinking  
24 about that.

25 The federal circuit has said that it generally applies

1 the collateral estoppel law of the circuit in which the case is  
2 pending. By circuit, I mean, in this case, the Third Circuit.  
3 However, the federal circuit has on issues that are peculiar to  
4 patent law, said on a number of instances, we're going to apply  
5 our own law.

6 And there are several cases --

7 THE COURT: Even on something like collateral  
8 estoppel?

9 MR. COHEN: Well, yeah, but -- as it applies to --  
10 federal circuit law governs the interpretation of claims of the  
11 patent. There are several federal circuit cases and we've cited  
12 them, involving the issue of the application of collateral  
13 estoppel to claim interpretation in another case.

14 And the federal circuit --

15 THE COURT: Even with the same plaintiff this is a  
16 different -- you know, in other words, you're both the same  
17 plaintiff, although we know that if it were an issue of another  
18 plaintiff, it's one thing --

19 MR. COHEN: No, but --

20 THE COURT: -- but I can tell you under Pennsylvania  
21 law, if this were interpreted -- and I don't know about that  
22 difference between district court and -- I haven't made up my  
23 mind about -- and appellate court, that there's no question  
24 that you could be collaterally estopped from -- in a different  
25 case --

1 MR. COHEN: But it's --

2 THE COURT: -- from -- from making the same assertion.  
3 I happen to have written on that when I was at state court,  
4 that's how I know -- happen to know about it.

5 MR. COHEN: But under the federal -- under the federal  
6 circuit cases we've cited, the federal circuit had said, we're  
7 not going to apply collateral estoppel, unless the decision was  
8 essential to the judgment in the other case. And if the case  
9 goes up on appeal -- and this is also directly out of the  
10 Restatement -- if the district court judge gives two or three  
11 grounds for his decision and it goes up on appeal and only one  
12 of those grounds is affirmed, it's affirmed on one ground.  
13 Whereas, here the other ground -- the ground that they're  
14 arguing collateral estoppel --

15 THE COURT: I understand all that.

16 MR. COHEN: -- wasn't decided. The federal circuit --

17 THE COURT: I read both cases, so.

18 MR. COHEN: -- the federal circuit has said in a very  
19 recent case, we're not going to apply collateral estoppel.

20 THE COURT: And you have that case cited?

21 MR. COHEN: We have the case cited.

22 THE COURT: All right.

23 MR. COHEN: It's the Masco (ph) case.

24 THE COURT: Okay. Do you want -- what?

25 MR. COHEN: It's the Masco case.

1 THE COURT: Okay. Do you want to respond to that?

2 MR. SILVER: Well, just briefly.

3 I mean, if you look at the -- the collateral estoppel  
4 issues that we're asking the Court to find, they're not solely  
5 just on claim interpretation, they're responses to requests for  
6 admission on scientific principles. That -- that has --

7 THE COURT: Well, that comes down the pike, that's as  
8 far as summary judgment is concerned --

9 MR. SILVER: Right.

10 THE COURT: -- and that as far as --

11 MR. SILVER: But it's also relevant to how you would  
12 construe the claims in view of their admissions on what certain  
13 things do or cannot do in their -- as set forth in their patent  
14 on what can and cannot be a wetting agent.

15 I mean, your -- one of your goals is to construe what  
16 is a wetting agent according to this patent?

17 Now, they've made certain admissions in their prior  
18 case -- factual admissions, scientific admissions -- that are  
19 contrary to the position that they're now taking based on  
20 scientific information.

21 So, it's -- it's not only an issue of claim  
22 construction, but it's one of an underlying factual assertion.

23 THE COURT: What's your position on that?

24 MR. COHEN: We disagree with that. And I could go  
25 into it, but we absolutely disagree with that on claim



1 interpretation -- on claim interpretation --

2 THE COURT: Yes.

3 MR. COHEN: There is nothing that we said or did in  
4 the other case, that would collaterally estop us in this case  
5 under federal circuit precedent.

6 I think --

7 THE COURT: But in other words, this is not a matter  
8 of collateral estoppel, 'cause that's a Court -- a Court  
9 determination. He's saying to you that you are, in fact -- as a  
10 matter, estopped from making some kind of assertion in the  
11 underlying litigation that you're not making here?

12 MR. COHEN: Well, the only -- as applied to claim --  
13 to claim interpretation, I think the answer is, absolutely not.  
14 In the summary judgment briefs, there were some allegations as  
15 applied to the issue of infringement, which is a different  
16 issue --

17 THE COURT: That's what I --

18 MR. COHEN: -- and we also disagreed with that. But  
19 I'm not prepared to argue that today.

20 THE COURT: All right, okay. All right, okay.

21 I will make a -- I will -- I'm trying to see whether  
22 or not, I need a hearing. This is what -- why I had to have you  
23 come in today, because it may be that I can decide everything on  
24 the papers. Okay. All right.

25 Interpretation of the claim. I want you to -- are you

1 prepared today to argue the interpretation of the claim and I  
2 will start with you -- on taking the patent -- let me have --  
3 and telling me -- running through it with me so to make sure I  
4 understood it -- where is my patent --

5 (Discussion held off the record.)

6 THE COURT: Now, first of all, let's -- tell me what  
7 your argument is in the difference of 505 or 791, I didn't catch  
8 that at all, Mr. Cohen. You're saying to me that they can't  
9 file a claim on 505, isn't that what you're basically --

10 (Pause.)

11 THE COURT: I'll give you a second.

12 MR. SILVER: Oh, pardon me, yeah.

13 THE COURT: Would you like -- would you like to do all  
14 this at the time of the Markman hearing?

15 MR. SILVER: Well, I mean, I think -- I think I can  
16 give you our basic --

17 THE COURT: Okay.

18 MR. SILVER: -- argument because it's relatively  
19 straightforward.

20 If you -- if you look at the two patents that are  
21 involved in suit, the 505 and the 791, they say you had this  
22 pharmaceutical composition --

23 THE COURT: Oh, so, we're all ready for me to  
24 entertain the 505, then? You had some arguments that I didn't  
25 catch --

1 MR. SILVER: Well -- our argument was when we filed  
2 our abbreviated new drug application, the statute says, you must  
3 certify the patents that are listed in the Orange Book.

4 THE COURT: In the Orange Book, whatever that is.

5 MR. SILVER: And only one of the two patents are  
6 listed in the Orange Book.

7 THE COURT: But they say, they dovetailed, so you're  
8 not --

9 MR. SILVER: Well, so -- since we figured, we'd  
10 resolve -- we could move to dismiss one the patents, we figured,  
11 we'll just get it all over with at once --

12 THE COURT: All right. Okay.

13 MR. SILVER: -- even though we don't believe there was  
14 proper jurisdiction --

15 THE COURT: All right, okay.

16 MR. SILVER: -- for the second patent.

17 THE COURT: So, you'll -- we're on the record now, you  
18 want me to interpret both --

19 MR. SILVER: Yes.

20 THE COURT: -- both -- you're making no claim that I  
21 should not be interpreting both patents?

22 MR. SILVER: Right.

23 THE COURT: And, obviously, there's a lot of  
24 similarity between two patents.

25 MR. SILVER: Yes.

1 THE COURT: So, let's go -- since 791 is a direct  
2 issue of the -- of the wetting agent and one claim, let's talk  
3 about that.

4 MR. SILVER: Okay. Well, when you --

5 THE COURT: Well, no -- no, the plaintiff is going to  
6 go first on this issue.

7 MR. COHEN: Okay.

8 Actually, I'm going to talk about wetting agent in  
9 terms of both the 505 and the 791 patents, because the two  
10 patents derive from -- they're based on the same application.

11 THE COURT: Well, let's start with 791 --

12 MR. COHEN: Okay.

13 THE COURT: -- if you don't mind.

14 MR. COHEN: All right.

15 (Pause.)

16 THE COURT: It is clear, that's one claim, the only --

17 MR. COHEN: Right.

18 THE COURT: -- independent claim is --

19 MR. COHEN: Well, it --

20 THE COURT: -- is Claim 1, isn't that correct?

21 MR. COHEN: Yes.

22 Wetting agent has to be interpreted the same for the  
23 791 and the 505 patents, because they're related applications.  
24 There's federal circuit law on that.

25 THE COURT: Is that correct?

1 MR. SILVER: I wouldn't disagree with that.

2 THE COURT: All right. Okay.

3 MR. COHEN: Okay.

4 THE COURT: I just want to know what you agree with  
5 and what you don't.

6 MR. COHEN: Okay.

7 They raise the issue of whether wetting agent as it's  
8 used in the claim includes sugars. The federal circuit --

9 MR. SILVER: I -- I disagree with --

10 THE COURT: No, that's not what they said.

11 MR. SILVER: We did not raise that issue, your raised  
12 it.

13 THE COURT: No. That's not so -- that isn't so, they  
14 simply said that -- your argument -- as I understand it was -- a  
15 Markus (ph) argument.

16 UNIDENTIFIED COUNSEL: Marcush (ph).

17 MR. SILVER: Marcush.

18 THE COURT: Marcush.

19 UNIDENTIFIED COUNSEL: Marcush.

20 THE COURT: I know what it is, I read the -- I read  
21 that --

22 MR. COHEN: Okay.

23 THE COURT: -- that -- the little bit from the Patent  
24 Office that explains Marcush, so I know what it is.

25 MR. COHEN: Judge, they've argued that, regardless of

1 whether the term is included in the Marcush group, they have  
2 definitely argued and their expert has testified that the sugar  
3 is not a wetting agent.

4 Our response to that is, that the term -- that the  
5 patent --

6 THE COURT: That's irrelevant to me now.

7 MR. COHEN: That the --

8 THE COURT: This is absolutely irrelevant to me. The  
9 only thing that matters to me is how I define wetting agent.

10 MR. COHEN: I'm getting to that.

11 THE COURT: All right.

12 MR. COHEN: The specification says -- that is, the  
13 part of the patent, not the claim -- says among the wetting  
14 agents associated with diltiazem are the following component may  
15 more particularly be exemplified and then it says, sugars.

16 So, it says right in the specification that wetting  
17 agent includes --

18 THE COURT: Where -- where are you reading from,  
19 let's read it. 791 --

20 MR. COHEN: I'm -- I'm looking at the 505 patent and  
21 then, if you look at the seven --

22 THE COURT: No, look at 791.

23 MR. COHEN: Okay. They're both derived from the same  
24 specification.

25 THE COURT: All right.

1 MR. COHEN: Among the wetting -- if you look at Column  
2 3 on the 791 patent --

3 THE COURT: Okay.

4 MR. COHEN: There was -- and there was an amendment  
5 that was made in the first page of the specification, which was  
6 inadvertently not made.

7 Among -- look at Column 3, starting at line 14:

8 THE COURT: Hm-hmm.

9 MR. COHEN: Among the wetting agents associated with  
10 the diltiazem or soaker in the beads, the following  
11 compounds may more particularly be exemplified.

12 Then it says, sucrose, mannitol, sorbitol (ph) all  
13 three of which are sugars.

14 That is the basis for the words, sugars in the Marcush  
15 group in Claim 1, which you will find at Column 9, Line --  
16 beginning at Line 7, when the wetting agent is selected from the  
17 group consistent of sugars.

18 THE COURT: There's no question that -- as far as I  
19 read this -- that that the wetting agent is selected from the  
20 group of sugars. That does not mean, logically, that if you're  
21 a sugar, you're part of that group.

22 MR. COHEN: Yes, it does, absolutely, it has to be.

23 Wetting agent -- it says in the patent -- that a  
24 wetting agent includes sugars. What are we talking about?

25 THE COURT: Where does it say that? I don't see where

1 it says that.

2 Among the wetting agents -- the bond may be  
3 particularly exemplified as a sugar.

4 MR. COHEN: That's exactly right.

5 THE COURT: Well, that means that a sugar could be a  
6 wetting agent, but just because the sugar could be a wetting  
7 agent doesn't mean that all wetting agents are sugars.

8 MR. BERKOWITZ: Correct.

9 MR. COHEN: No --

10 THE COURT: That's where the --

11 MR. COHEN: No, no, no -- but that -- we're not  
12 talking about all wetting agents here. Because in this claim  
13 wetting agent is restricted to the terms that are in the Marcush  
14 group, because there's lots of other things that are wetting  
15 agents that are not in the Marcush group.

16 THE COURT: Yeah. But it has to be -- it has to be a  
17 wetting agent.

18 MR. COHEN: The --

19 THE COURT: I mean, first, I have to decide whether  
20 it's a wetting agent, don't I?

21 MR. COHEN: Well, no, it's defined in the patent as a  
22 wetting agent. It's defined because in that -- in that part of  
23 the specification I read to you -- and if you look back at the  
24 505 specification, where it -- it explicitly said, sugars and  
25 that's because the -- the specification was amended. And you've



1 got to construe wetting agent the same for both patents, because  
2 they're related. There's federal circuit law on that.

3 If the specification says that a wetting agent  
4 includes sugars -- and that's exactly what it says -- then the  
5 inventor -- what the inventor intended to convey was, for this  
6 invention wetting agent --

7 THE COURT: Something is coming off -- is it my -- is  
8 it my --

9 (Discussion held off the record.)

10 MR. POKOTILOV: I'm glad to see I'm not the only  
11 one --

12 (Laughter.)

13 (Counsel speaking simultaneously.)

14 MR. COHEN: If I may continue, for this invention,  
15 wetting agent includes sugars.

16 Now, why is he saying that? Because we're not talking  
17 about wetting agent in the theoretical sense where you take a  
18 glass of water and put something in it and see if it -- if it  
19 affects the surface tension. Surface tension is absolutely  
20 irrelevant in this invention, because what happens? We're  
21 looking at a bead and in the bead -- the patent -- 'cause you've  
22 got diltiazem, which is the activity ingredient and it's got to  
23 be a homogeneous mixture of diltiazem and a wetting agent, when  
24 is it going to get wet? It's going to get wet after it's  
25 ingested, when the gastric fluid permeates the membrane.

1 And now, what is the purpose of the wetting agent?  
2 Well, it tells us in the claim of the 791 patent, it's to  
3 maintain the solubility of diltiazem in the gastrointestinal  
4 tract. In other words, inside of this membrane, which is a  
5 boundary, you've got the water coming in to the membrane and --  
6 and sugar acts as a wetting agent, not generally, but with  
7 respect to this particular active ingredient, diltiazem, it acts  
8 as a wetting agent.

9 THE COURT: You want me to say -- you want me to say  
10 at this stage without defining wetting agent, that sugar is a  
11 wetting agent?

12 MR. COHEN: For purposes of this claim for this  
13 patent, it is the defined as a wetting agent, based on the  
14 specification and the language of the claim.

15 And that's what the federal circuit said in the  
16 Florida case in its footnote, when it says that --

17 THE COURT: Give me the page.

18 (Discussion held off the record.)

19 THE COURT: Yeah -- we're -- I have the two pages --

20 MR. SILVER: It's Iodel versus (ph) --

21 (indiscernible) --

22 THE COURT: Here, one second -- I have it -- I have  
23 it. What page and what footnote?

24 MR. COHEN: I have --

25 THE COURT: Well, Footnote 1:

1           ...the outcome of this case does not hinge on whether  
2           the sugar used core of the Andrx product meets the wetting  
3           agent limitation of Claim 1 of the 791 claim.

4           MR. COHEN: Wait --

5           THE COURT: If intrinsic evidence including the Mar --  
6           the list of the wetting agents in the specification  
7           unambiguously define the term, wetting agent.

8           MR. COHEN: That's it.

9           THE COURT: Then the district court's reliance on  
10          expert testimony construes this term was a problem.

11          MR. COHEN: In other words, in that case, the court  
12          didn't decide the -- the federal circuit didn't decide the issue  
13          here, because it decided that we had failed to prove that there  
14          was a homogeneous mixture in the gastrointestinal tract.

15          THE COURT: But then, they did that without doing a  
16          Markman, because -- I mean, they decide the factual issue.

17          MR. COHEN: They decided the issue of infringement  
18          without deciding --

19          THE COURT: That's what I said.

20          MR. COHEN: -- whether or not --

21          THE COURT: Yes.

22          MR. COHEN: -- this was a wetting agent.

23          THE COURT: Well, that's what I said, they decided --

24          MR. COHEN: But they --

25          THE COURT: -- the factual issue.

1 MR. COHEN: -- but the federal circuit said -- because  
2 the trial judge has said, it's not a wetting agent and based on  
3 the testimony of an expert and their observation here is that --

4 THE COURT: I don't know -- I don't know if they did  
5 it based upon ethics, they said they -- they're not construing  
6 it's the patent.

7 MR. COHEN: The trial judge did it based on testimony  
8 of the expert -- I tried the case.

9 THE COURT: Also -- well, that doesn't mean anything  
10 -- but also, you know, you --

11 MR. COHEN: You know --

12 THE COURT: -- you know, you'll forgive me.

13 But also dictionary and other things. I mean, they  
14 looked at extrinsic evidence, there's no question about that.

15 MR. COHEN: But you only look at extrinsic evidence,  
16 your Honor, if -- if the intrinsic evidence --

17 THE COURT: There's no --

18 MR. COHEN: -- leaves an ambiguity.

19 THE COURT: That's correct.

20 MR. COHEN: What we're saying here, the specification  
21 by saying wetting agents include sugars -- it says it in the  
22 specification -- if that's what it says, then the patentee has  
23 decided to be his own lexicographer and say for this particular  
24 active ingredient, sugar is a wetting agent.

25 Look, it's not --

1 THE COURT: I want to see where it is -- I -- I just  
2 want to see what language precisely -- because I'll understand  
3 it -- I don't want to go back and then mumble to myself.

4 MR. COHEN: Look --

5 THE COURT: So, I want you to tell me --

6 MR. COHEN: Look at Column --

7 THE COURT: I want you to tell me what precisely --  
8 Column 3 of -- this is 791 --

9 MR. COHEN: I want to start with the 505 patent,  
10 because that comes first, it's first in the line, it was the  
11 first thing that was granted by the patent office and the 505 --

12 THE COURT: Is the -- is the participation different  
13 in 505 --

14 MR. COHEN: It's exactly the same.

15 THE COURT: -- according to you in --

16 MR. COHEN: It's got to be the same.

17 THE COURT: --- 791 -- then, do 791 for me, 'cause  
18 that's the one I've studied.

19 MR. COHEN: Okay. Well, the only thing is that the  
20 word, sugars was added by amendment in the specification in the  
21 505 patent.

22 THE COURT: Well, okay. I'll take a look at that.

23 MR. COHEN: Okay.

24 THE COURT: But if they say something different, I  
25 have to rule -- I assume, I have to -- I have to interpret them

1 differently.

2 MR. COHEN: Well, it says -- no --

3 THE COURT: Well, where's -- where's the 505 -- I'll  
4 go back to your 505 and then, you're going to walk me through  
5 the other.

6 What is it on 505 -- tell me again?

7 MR. COHEN: Column 3 -- Column 3 --

8 THE COURT: Yes.

9 MR. COHEN: -- Line -- beginning with Line 12.

10 THE COURT: Line 12. Among the --

11 MR. COHEN: Among the wetting agents associated with  
12 diltiazem or a salt thereof in the beads, the following  
13 compounds may more particularly be exemplified --

14 And then it says, sugars, for example, sucrose,  
15 mannitol, sorbitol and lactose.

16 THE COURT: Now, is this subsequent -- was this --

17 MR. COHEN: This was --

18 THE COURT: -- subsequently -- subsequent to this 791?

19 MR. COHEN: No, this was before, this was granted  
20 before --

21 THE COURT: It was before. So, it changed it?

22 MR. COHEN: This was granted -- they change the  
23 specification and they, inadvertently, didn't put the same  
24 amendment in.

25 THE COURT: How do I know that?

1 MR. COHEN: Because it's in the prosecution history.

2 THE COURT: That they made a mistake?

3 MR. COHEN: Well, it's clear, they -- they amended the  
4 specification in the 505, didn't make the same amendment in the  
5 791, but it was because it was a -- one is a continuation of the  
6 other.

7 THE COURT: All right.

8 MR. COHEN: And, you know, we'll have to go through  
9 the -- I want -- what I want to do in the Markman hearing is go  
10 through the prosecution history and show chronologically, what  
11 happened in the patent office and how it might -- because it's  
12 part of the intrinsic -- intrinsic evidence that --

13 THE COURT: That's all right.

14 MR. COHEN: -- your Honor needs to -- to --

15 THE COURT: Okay.

16 MR. COHEN: -- take into consideration.

17 THE COURT: Okay.

18 MR. COHEN: So, here it's saying, sugars and it's  
19 saying that that -- that, for example, sucrose, mannitol,  
20 sorbitol which are all listed in the specification of the 791  
21 patent, which we've just looked at, they're all sugars.

22 So, the Marcush group in the 791 patent says, sugars.  
23 It doesn't say -- if you look at the 791 patent now in Column 3  
24 -- Column 3 starting at Line 14 it says:

25 Among the wetting agents associated -- associated --

1 with the diltiazem or salt in the beads.

2 The following compounds may more particularly be  
3 exemplified -- it says -- sucrose, mannitol, sorbitol, they're  
4 all sugars. That's how sugars gets into the claim.

5 THE COURT: Well, you -- walk me through it again,  
6 because the language is difficult for me --

7 MR. COHEN: Right.

8 THE COURT: -- because I'm not a patent lawyer, okay.

9 MR. COHEN: Well, it's --

10 THE COURT: You have to understand that.

11 MR. COHEN: Right.

12 THE COURT: What -- what is your reading of:

13 The following may particularly be exemplified.

14 What --

15 MR. COHEN: It's like saying, examples of wetting  
16 agents that are associated with diltiazem.

17 I mean, this is --

18 THE COURT: All right.

19 MR. COHEN: -- it has nothing to do with patent law.  
20 This has something to do with a guy, who can't write English. I  
21 mean, this is not -- you know -- it's just -- it's typical,  
22 unfortunately --

23 THE COURT: But it's --

24 MR. COHEN: -- of what goes in the patents, but  
25 it's --



1 THE COURT: Well, I know that, but I have to be able  
2 to understand it.

3 MR. COHEN: Well, it's -- you know --

4 THE COURT: Okay.

5 MR. COHEN: -- a fair reading of that and translated  
6 into lay English would be, that examples of wetting agents  
7 associated with diltiazem are -- and then, the first line is  
8 sucrose, mannitol, sorbitol. Our expert would testify and you  
9 could find dictionary definitions, they're all sugars.

10 And so, in the Marcush group then, it says, wetting  
11 agents selected from the group consisting of sugars. So,  
12 wetting agents selected from the group, so sugar by definition,  
13 since wetting agent can be selected from the group consisting of  
14 sugars, sugar by definition in that construct is a wetting  
15 agent. It's got to be, otherwise, why would --

16 THE COURT: All sugars?

17 MR. COHEN: All sugars.

18 There's nothing in this -- there's nothing in the  
19 prosecution history, nothing in the specification that indicates  
20 any intention by the patentee to restrict sugars to anything  
21 other than sugars.

22 And that's -- because you give three --

23 THE COURT: Well, then you go back to whether or not  
24 there's a patent.

25 MR. COHEN: Well, that's -- that's an invalidity

1 argument that -- that really doesn't get -- it's really not  
2 appropriate for a Markman hearing, but the Markman --

3 THE COURT: I --

4 MR. COHEN: -- hearing is construing the -- we have to  
5 construe the claims, before you can decide whether or not --

6 THE COURT: All right. I have to --

7 MR. COHEN: -- they're invalid.

8 THE COURT: I think I understand that -- I understand  
9 that.

10 MR. SILVER: Well, your Honor, to the extent you  
11 construe the claims, the case law says, you're to construe them  
12 to uphold validity. So, if they're -- I mean, when you look at  
13 this -- well, first of all, I don't know why you would have to  
14 construe the word, sugar. In my view, you don't have to. Okay.

15 Secondly, there are thousands of --

16 THE COURT: What do you mean -- what do you mean by  
17 that, why don't --

18 MR. SILVER: It's not -- the question to me is -- is  
19 not whether sugar is a wetting agent, the question in my mind is  
20 whether methyl cellulose is a wetting agent. So, in our mind,  
21 sugars is out of the picture.

22 THE COURT: Well, he said that -- in the -- wait a  
23 minute. In his patent, he says that all sugars -- all sugars --

24 MR. SILVER: Well, then you know what, they're -- look  
25 at the prior art then. I mean, sugars is a -- is a broad

1 classification. There are tens of thousands of sugars. You  
2 mean to tell me that this inventor envisioned in his mind that  
3 every single of tens upon thousands of sugars are going to work  
4 in this invention?

5 And, in fact, if you look at our -- our declaration of  
6 Dr. Metra (ph), he tested sugars and showed they can't be acting  
7 as a wetting agent.

8 So, first of all, in our view, you don't have to  
9 construe sugars, because the question in our mind is, is methyl  
10 cellulose a wetting agent? And when you look at their patent  
11 nowhere anywhere in their patent do they say, methyl cellulose  
12 is a wetting agent, in fact, if you look at the 79 -- 791 --

13 THE COURT: Well, yeah, but he says -- wait a minute.  
14 Let me argue -- he said that in looking at the 79 -- let's look  
15 at three --

16 MR. SILVER: 03.

17 THE COURT: Column 3.

18 MR. SILVER: It lists all the potential wetting  
19 agents --

20 THE COURT: Yes, that's --

21 MR. SILVER: -- and methyl cellulose is not listed  
22 there.

23 And, in fact, go down to Line 32 --

24 THE COURT: But then, in the other one, he says,  
25 sugars are --

1 MR. SILVER: Yeah. But it doesn't say methyl  
2 cellulose --

3 MR. COHEN: Well, the issue --

4 MR. SILVER: -- it says, sugars.

5 MR. COHEN: Excuse me. The issue of whether methyl  
6 cellulose is a sugar is a fact question. It's really an  
7 infringement issue, it's not -- it's not a claim interpretation  
8 issue.

9 THE COURT: Well, that's -- what's your position on  
10 that?

11 MR. SILVER: Our position is, is that we're looking at  
12 methyl cellulose, not sugar. So, if you don't find in the  
13 patent or the file history that methyl cellulose is disclosed as  
14 a wetting agent, then you should construe the claim term such  
15 that the claims does not include methyl cellulose as a wetting  
16 agent.

17 In fact, when you look --

18 THE COURT: Well, there's no question that I'm not  
19 going to do that. I'm not going to say anything about methyl  
20 cellulose, but I -- the question becomes, can -- do you believe  
21 -- according to -- I'm not going to say anything about methyl  
22 cellulose, but in fact, I believe -- right -- I believe I'm  
23 correct in believing that that is a down-the-pike issue.

24 But the question here is whether I interpret the  
25 patent to say that a -- that the wetting agent -- that all

1 sugars are wetting agents, whether I decide that methyl  
2 cellulose is a sugar is something else, that's a down-the-pike  
3 issue and I'd agree with you that that doesn't -- that that -- I  
4 think there's no dispute about that it is, but that's not what I  
5 have to do yet.

6 But he -- Mr. Cohen -- is suggesting that all sugars  
7 are wetting agents according to 505. Now, I don't see it.

8 MR. SILVER: I don't see it, either, your Honor. I  
9 mean, when you look at Column --

10 THE COURT: Well, I don't see it in --

11 MR. SILVER: -- Column 3 --

12 THE COURT: -- except in that one.

13 MR. SILVER: -- it's says -- it lists three of them,  
14 it doesn't list tens of thousands of sugars, it lists three of  
15 them.

16 MR. COHEN: But it uses the word, example, exemplified  
17 means example.

18 THE COURT: Yes.

19 MR. COHEN: You don't have -- I mean, you can't  
20 require -- and there's cases on this and I can give them to your  
21 Honor -- you can't require patentees to list every possible  
22 example of everything that might work. A patent specification  
23 is not like -- it's not like a recipe in a cookbook, where you  
24 list everything particularly how you do it. You have to --

25 THE COURT: But it's hard for me to believe that you

1 would -- that you would be allowed to say, all sugars. I mean,  
2 I have to say it, if -- I may interpret it that way and then,  
3 down the pike, change -- say that just couldn't be, because --  
4 because it's just too broad.

5 MR. COHEN: Well, I -- I -- there's nothing -- there's  
6 nothing in -- there's no evidence that suggests that with  
7 respect to diltiazem, sugars is too broad. That's something --  
8 if -- if it says, sugars then, the federal circuit says, it  
9 means just what it says, sugars. There's no limitation anywhere  
10 in the specification or in the prosecution history as to what  
11 kind of sugars. There's no limitation in the claim.

12 But the federal circuit says, that you use words like,  
13 sugar, you give them their ordinary meaning. You can't -- and  
14 for better or for worse -- sugars means sugars.

15 But the issue as to whether sugar is a wetting agent  
16 in this claim, we say that it's very clear from the  
17 specification, which says that one -- the examples of the  
18 wetting agent and in the 791 patent, it gives three different  
19 kinds of sugars and in the 505 patent, it expands it and says,  
20 sugars.

21 And you've got to construe that because these are  
22 related applications -- and I can give your Honor a case on this  
23 -- you've got to construe wetting agent the same.

24 THE COURT: Well, no, he admitted to that. He said  
25 that that's true. Okay.

1 But the specification isn't the first thing I look to.  
2 The first thing I look to -- as I understand it -- is the claim.

3 MR. COHEN: Right.

4 THE COURT: Then, I go to the specification and then,  
5 I go to the --

6 UNIDENTIFIED COUNSEL: Prosecution history.

7 THE COURT: -- to the prosecution.

8 MR. COHEN: Right.

9 THE COURT: So, the first thing I have to do is look  
10 -- and let's got to 791, 'cause it's only one claim and it's the  
11 only outstanding claim.

12 MR. COHEN: Right.

13 THE COURT: And that says -- pharmaceutically --

14 MR. COHEN: It's actually on -- the phrase that we're  
15 talking about is actually on Column 10.

16 MR. SILVER: Column 9.

17 THE COURT: No, Column 9.

18 MR. COHEN: Column 9, I -- I mean, it's on the last  
19 page.

20 THE COURT: What is claimed as new and desired to be  
21 secured by the letters patent.

22 That's what's new -- that's what the --

23 MR. COHEN: Right.

24 THE COURT: -- this is what it's all about.

25 MR. COHEN: Right.

1 THE COURT: An extended release --

2 Don't make me say all the words.

3 -- composition of one or more  
4 pharmaceutically-acceptable salts -- of diltiazem -- which  
5 comprises D -- containing an effective amount of one or more  
6 diltiazem salt as the active ingredient, which contains one  
7 or more...and an effective amount of a wetting agent.

8 A wetting agent -- of a wetting -- one or more of a --  
9 of a wetting agent in a mixture with one or more -- of the  
10 salts -- to maintain the solubility of diltiazem -- ensuring  
11 that the solubility of the diltiazem is unaffected by the ph  
12 of the gastrointestinal tract or that other adverse  
13 conditions which the composition will meet therein, that it  
14 be coated with a microporous membrane combining the -- of a  
15 water soluble -- water dispersible polymer -- co-polymer --  
16 and water and -- and a pharmaceutical acceptable adjunct  
17 (ph) .

18 What does that mean?

19 MR. SILVER: Carrier or --

20 MR. COHEN: That's the carrier, it's just excipient.

21 THE COURT: And wherein the wetting agent is selected  
22 from the group consisting of sugars.

23 And it says, wherein the wetting agent is selected  
24 from the group consisting of sugars and a lot of other things.

25 MR. COHEN: That's the definition of wetting agent.



1 THE COURT: That's -- wherein --

2 MR. COHEN: It's right in the claim.

3 THE COURT: -- the wetting agent is selected from --  
4 it's selected from the group, it doesn't mean that everything in  
5 the group is a --

6 MR. COHEN: It means, you can select the wetting agent  
7 from the group --

8 THE COURT: -- is a wetting --

9 MR. COHEN: -- consisting of sugars.

10 In other words, if it's a sugar, it can be a wetting  
11 agent for the purposes of this claim. Nothing in this claim  
12 says that it isn't all sugars.

13 THE COURT: Well, the -- unless you -- unless you  
14 define -- you say that this does not define a wetting agent and  
15 then, you can define that -- that the wetting agent is something  
16 different and this is just one of the sugars.

17 Well, I think I understand the issue and you'll  
18 forgive me, I think I understand the issue.

19 And it will be something that will have to be  
20 determined. I'm not sure that a Markman hearing is going to  
21 help me on this.

22 Now, you want -- you believe it will? Or not a  
23 Markman hearing. I mean, at least, it would be a Markman  
24 argument or something more than you have today?

25 MR. COHEN: Well, I -- I think an argument, something

1 organized, where we could do a little bit of presentation might  
2 help.

3 I guess, my question to your Honor -- and -- one of  
4 the questions that Mike -- Mike Berkowitz -- and I have  
5 discussed -- was whether it would be helpful to your Honor to  
6 have experts here.

7 And in that regard, we view expert testimony at a  
8 Markman hearing -- and the federal circuit has explained this --  
9 is something to help the Court with the science. In other  
10 words, the -- not so much that the expert should define the  
11 terms, but that the experts should be able to explain the  
12 technology and we would be prepared to have Dr. Yakowski (ph)  
13 explain just the background of this technology, what's the --  
14 what a microporous membrane is, what's in the core, that the  
15 microporous membrane surrounds and just what some of these other  
16 terms --

17 THE COURT: I've never had any objection to becoming  
18 educated. Do you have any objection to my --

19 MR. SILVER: Well, your Honor, we're prepared to help  
20 you in any way you feel, so we're prepared to bring our experts  
21 as well.

22 THE COURT: Okay.

23 MR. SILVER: We have two experts and I guess, you  
24 know, we didn't know whether you wanted something --

25 THE COURT: Well, I have been trying to figure that

1 out today.

2 MR. SILVER: Right.

3 THE COURT: That's why we're -- that's why we're here.

4 I'm not sure it's going to be terribly helpful, but I  
5 never -- sometimes, it is and I have had that, where sometimes  
6 -- because then, when I see the terms, I don't feel overwhelmed  
7 by them and I usually don't mind having someone just enlighten  
8 me about the -- the general science of this -- of this  
9 particular -- this particular patent.

10 I mean, I don't -- I don't object to that. I don't  
11 know how helpful it's going to be, frankly, in my figuring out  
12 what it's about, but sometimes when I see -- have a little bit  
13 of background, it is helpful. And I would not object to it.

14 I don't want -- I want one person from each side or  
15 both of you could agree on someone, who could come in and  
16 educate me, that would be very helpful, just about what this  
17 patent is about. What it does, what happens --

18 MR. SILVER: Well, how -- may I, your Honor, if I may.

19 THE COURT: Yeah.

20 MR. SILVER: What sort of time frame are you looking  
21 at as for --

22 THE COURT: A morning.

23 MR. SILVER: A morning. So, you -- okay.

24 THE COURT: I don't want to do -- I mean, I -- that's  
25 what I'm looking at.

1           Then, I will decide. So, I think that maybe the two  
2 of you could get together on one person, who is going to tell it  
3 to me or if you need -- both of you need one, that would be all  
4 right for me, too. I don't -- what are you suggestions?

5           MR. COHEN: I think that -- right now, we each have  
6 experts that we've prepared, but perhaps, Mr. Silver and I could  
7 see if we could agree on --

8           MR. SILVER: Well, the only other option, I've used in  
9 other cases, your Honor, is where the parties agree upon a  
10 neutral person, that they each split the --

11          MR. COHEN: That's what I was gong to suggest.

12          MR. SILVER: -- they --

13          THE COURT: That's what I --

14          MR. SILVER: -- they each split --

15          THE COURT: That would really be better.

16          MR. SILVER: -- and without knowing the underlying  
17 reasons for the lawsuit, to just explain --

18          THE COURT: That would be very --

19          MR. SILVER: -- to you --

20          THE COURT: -- helpful.

21          MR. SILVER: -- the technology without any bias  
22 towards one side or the other.

23          THE COURT: I would really appreciate that, that would  
24 be very helpful.

25          MR. SILVER: And -- and I mean, the other thing is,

1 you know, if we were to go that route, one thing I've found that  
2 judges also may appreciate is not only using that person for the  
3 Markman, but if the Judge wanted to use that person throughout  
4 the litigation to consult on scientific issues, that would be an  
5 option, but we can discuss that later on.

6 THE COURT: Well, you know, the National Science  
7 Foundation -- Institute -- or -- Judge Pollak -- whatever Judge  
8 Pollak has -- and I have it somewhere -- had a whole list of  
9 experts, if the two of you want to take a look at this.

10 MR. SILVER: Well, the --

11 THE COURT: Do you know anything about that -- about  
12 that --

13 MR. COHEN: Sure. But I think if we were going to go  
14 this route, it would better to find somebody, who was local --

15 THE COURT: That's --

16 MR. COHEN: -- and then --

17 MR. SILVER: Yeah, the Philadelphia College of  
18 Pharmacy, something, but I don't think we could do it in the  
19 time frame we have for the Markman hearing.

20 THE COURT: Well, then we'll have to postpone -- then,  
21 we'll have to postpone it.

22 MR. COHEN: That was going to be my comment, too.

23 THE COURT: I have no problem with postponing it,  
24 because I want to be educated. I want to think about this in a  
25 -- in a rational way. If -- in fact, I was trying to deal with

1 the issue of collateral estoppel first, so that if it's -- if I  
2 decide -- even though wrongly --

3 (Laughter.)

4 THE COURT: -- that it was collaterally estopped -- it  
5 was collaterally estopped -- my -- then, I wouldn't have -- we  
6 wouldn't have to go through this. So, but I -- I just -- I'm  
7 telling you, my mind is very open on that issue and I have to  
8 read it, but it -- read the circuit court opinions on that  
9 issue. So, you can evaluate how strong or weak your positions  
10 are, after I read everything. I just read the two opinions that  
11 came down, I didn't read the whole body of law, so I had -- had  
12 to evaluate those.

13 So, I think that would be fine and I'd have no problem  
14 with -- with continuing the Markman hearing till both of you get  
15 together and then, call my Deputy, Marie and see whether you can  
16 set up a morning after you both have figured out who the joint  
17 expert would be.

18 And I think it is helpful to me to understand the  
19 technology and I'm sure it's helpful to you.

20 MR. SILVER: I mean, what we've -- what I've done in  
21 the past, your Honor, is both sides come up with an agreed list  
22 of topics --

23 THE COURT: Okay.

24 MR. SILVER: -- that are given to this person and that  
25 person will discuss those agreed-upon --

1 THE COURT: Opine on those.

2 MR. SILVER: -- topics.

3 THE COURT: Do we have any problem with that, Mr.  
4 Cohen?

5 MR. COHEN: Conceptually, no, but I'd want to talk to  
6 Mr. Silver --

7 THE COURT: Oh, well I --

8 MR. COHEN: -- and see what we can work out.

9 THE COURT: Well, put it this way, I want you to try  
10 and work it out. I will be here, I've never been -- I'm always  
11 available, you know, I'm not one of these people that says, I'm  
12 not going to discuss it. I'll do it over the telephone, it's  
13 not a great big deal. I've sat with you -- it's very helpful to  
14 me, because I kind of see where you're both coming from in a way  
15 that I didn't before, when I read the papers.

16 So, I would like -- I would very much like you to do  
17 that, Mr. Silver and also you, Mr. Cohen, okay?

18 MR. COHEN: Yes.

19 THE COURT: Now, what your agenda is to try and come  
20 up with an expert to outline the questions -- try and come up  
21 with an expert to outline the questions that you're going to  
22 address -- that this expert is going to address.

23 And I don't think -- unless they want to give me  
24 something, like -- sometimes -- you know, you'd be able to have  
25 an agreed-upon submission before, so they could show me -- I

1 have pictures and all this kind of stuff.

2 And then -- and then, have a day that I devote to  
3 that. At that same time, that I devoted to that, I probably  
4 will want you to formally address some of the issues that are in  
5 your briefs, okay, so that we can make it the same day. Maybe  
6 they could spend an hour on the -- on the presentation to me, if  
7 you could do it in an hour.

8 Then, maybe, we could have twenty minutes of an  
9 argument by you and twenty minutes by you and twenty minutes  
10 rebuttal, okay, to argue this -- the issues that are involved in  
11 this case, okay?

12 Now, if, in fact, I do my homework and I agree with  
13 defense on the -- my responsibility under collateral estoppel, I  
14 will let you know, okay?

15 MR. SILVER: Thank you, your Honor.

16 THE COURT: If I've had an opportunity to deal with  
17 that and I probably would have to write on it. Okay?

18 MR. COHEN: All right.

19 THE COURT: Anything else? If there's any -- I don't  
20 want you flying in from Chicago --

21 MR. COHEN: The -- the only thing that occurs to me  
22 with respect to the expert is, that if we have a disagreement  
23 and I can see one arising about the topics that the expert  
24 should address, perhaps, we can -- if we can't resolve it  
25 between ourselves, I think it would be important to get guidance



1 from the Court before we go through the -- before we retain the  
2 expert and get going.

3 THE COURT: Oh, you -- if you think you have it, send  
4 me what you're -- what -- I like it in writing in front of me,  
5 obviously, I prepare for what I have to do. And I would like --  
6 I would like it in writing to me and then, I'll have a telephone  
7 conversation. So, I can look at it and talk to you more  
8 intelligently. I can't talk to you on the phone about something  
9 I don't know anything about, okay? Does that sound right?

10 MR. COHEN: Hm-hmm.

11 MR. SILVER: Thank you.

12 THE COURT: Okay. So, we know what we're doing, we're  
13 continuing the Markman. You are going to do your homework and  
14 then, you're going to come back to Marie for a date for the  
15 Markman, okay, that's my Deputy -- secretary slash deputy.  
16 Okay.

17 And if you have any problems we can always talk first.  
18 Okay.

19 MR. COHEN: Okay.

20 THE COURT: That's my -- before August -- so, let's --  
21 we'll move it along.

22 (Laughter.)

23 MR. SILVER: As fast as possible.

24 THE COURT: All right.

25 (Adjourned in this matter at 2:43 p.m.)

C E R T I F I C A T E

I do hereby certify that the foregoing is a correct transcript from the electronic-sound recording of the proceedings in the above-entitled matter.



February 13, 2004

Gail Drummond  
28 8th Avenue  
Haddon Heights, N.J. 08035  
(856) 546-6270

**EXHIBIT F**

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BIOVAIL LABORATORIES, INC.  
a corporation of Barbados,

Plaintiff,

vs.

TORPHARM, INC., a Canadian  
Corporation,

Defendant.

No.: 02-7119

Judge: Anita B. Brody

**SCHEDULING ORDER**

This matter comes before the Court on the parties' request to enter a scheduling order. The parties through counsel have represented to this Court that they have agreed to a schedule. This Court has reviewed the parties' proposed schedule.

IT IS HEREBY ORDERED that the schedule for this case shall be as follows:

1. **The deadline for filing a motion for leave to amend the pleadings or to add any parties shall be April 30, 2003.**

2. **The first phase of fact discovery (prior to Markman claim construction hearing) shall be completed by April 30, 2003. Defendant has filed a motion for summary judgment of non-infringement for both patents-in-suit. The Court will resolve any claim construction issues raised in connection with Defendant's motion for summary judgment in a Markman hearing to be held commencing on May 19, 2003.**

3. **A Markman (claim construction) hearing shall be held to determine the meaning of any disputed terms of the claims of the patents-in-suit in connection with**

Defendant's motion for summary judgment, as follows:

- a. The Defendant has filed and served its opening brief, identifying its expert, and served its expert report as required by Rule 26(a)(2) on claim construction issues in the form of its Motion for Summary Judgment.
- b. The Plaintiff shall file and serve its responsive brief, identify any rebuttal experts, and serve any rebuttal expert reports required by Rule 26(a)(2) on claim construction issues by March 11, 2003.
- c. The Defendant shall file and serve its reply brief, identify any rebuttal experts, and serve any rebuttal expert reports required by Rule 26(a)(2) on claim construction issues by April 11, 2003.
- d. There shall be a pre-Markman hearing conference on May 8, 2003 at 10 a.m. in the courtroom of the Hon. Judge Anita B. Brody.
- e. The claim construction hearing shall be held on May 19 through 21, 2003. The parties expect that the hearing should take two days, and that live testimony and argument may be presented, to the extent Judge Brody permits

4. **A Second Scheduling Conference** if Defendant's Motion for Summary Judgment of Non-infringement is denied and shall be held following Court's ruling on claim construction issues to determine

- a. The need for any additional fact discovery and to set dates for expert discovery;
- f. The dates for the exchange of expert reports on infringement and validity

issues, and for depositions of such experts.

- g. The dates for identifying witnesses who may testify at trial and exhibits to be used at trial;
- h. The deadline for filing dispositive motions; and,
- i. The deadline for submitting the final pretrial order.

The following shall apply only if Defendant's Summary Judgment Motion is denied.

5. **Second Phase of fact discovery** (following claim construction ruling), if any, as determined by the Court at the Second Scheduling Conference.

6. **The maximum number of interrogatories by each party to any other party are fifty (50).**

7. **The maximum number of requests for admission shall be 100 per party.**

8. **Maximum number of depositions shall be as provided by the Federal Rules of Civil Procedure.**

9. **Experts.**

- a. Each party shall identify each expert who may provide expert testimony, and each party shall submit a report from each retained expert, as required under Rule 26(a)(2), on any issue on which that party bears the burden of proof, on a date set by the Court at the Second Scheduling Conference.
- j. Each party shall identify each expert who may provide rebuttal expert testimony, and submit a report from each retained expert under Rule 26(a)(2), on any issue in which a party does not bear the burden of proof,

by 30 days later.

k. The depositions of all experts shall be completed 30 days following the submission of rebuttal expert reports.

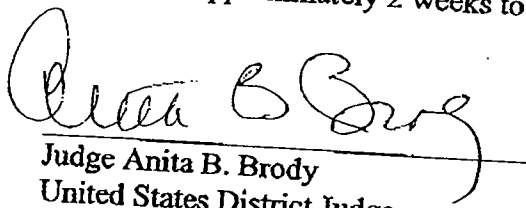
10. **Dispositive Motions.** All potentially dispositive motions should be filed no later than the date set by the Court in the Second Scheduling Conference.

11. **Final lists of witnesses and exhibits** under Rule 26(a)(3) shall be due by the parties on the date set by the Court in the Second Scheduling Conference, and each witness listed who has not yet been deposed may be deposed, notwithstanding any limit on the number of depositions.

12. **The final pretrial order** shall be submitted on the date set by the Court in the Second Scheduling Conference.

13. **The case should be ready for trial** by the date that the final pretrial order is submitted. The parties expect that this case should take approximately 2 weeks to try.

Dated: 12/19/02

  
Judge Anita B. Brody  
United States District Judge

Copies faxed on 12-20-2002 to:  
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EXHIBIT G



IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BIOVAIL LABORATORIES, INC.  
a corporation of Barbados

Plaintiff,

vs.

TORPHARM, INC., a Canadian  
Corporation,

Defendant.

Civil No. 02-7119

Judge: Anita B. Brody

**ANSWER TO AMENDED  
COMPLAINT FOR PATENT INFRINGEMENT,  
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendant, responds to the amended complaint as follows:

**JURISDICTION, VENUE, AND PARTIES**

1. Admitted.
2. Defendant is without sufficient information and belief as to the truth of the allegations of paragraph 2 and therefore denies those allegations.
3. Admitted.
4. Admitted.
5. No response is necessary as the allegation requires a conclusion of law.
6. Admitted with respect to Torpharm's registered agent. No response is necessary as to either personal jurisdiction or venue since these are conclusions of law.

**BIOVAIL'S NEW DRUG APPLICATION AND  
BIOVAIL'S RIGHTS UNDER THE '791 PATENT**

7. Admitted that U.S. Patent No. 5,529,791 ("the '791 patent") issued on June 25, 1996. Regarding the remaining allegations, Defendant is without sufficient information and belief as to the truth of the remaining allegations of paragraph 7 and therefore denies those allegations.

8. Admitted that U.S. Patent No. 5,288,505 ("the '505 patent") issued on February 22, 1994. Regarding the remaining allegations, Defendant is without sufficient information and belief as to the truth of the remaining allegations of paragraph 8 and therefore denies those allegations.

9. Defendant is without sufficient information and belief as to the truth of the allegations of paragraph 9 and therefore denies those allegations.

10. Admitted.

**TORPHARM'S ACT OF PATENT  
INFRINGEMENT UNDER 35 U.S.C. §271(e)(2)**

11. Admitted that TorPharm advised Plaintiff by means of a letter dated July 16, 2002, that Torpharm had filed Abbreviated New Drug Application ("ANDA") No. 76-395 to market a generic version of Diltiazem HCl Capsules Type TZ (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg, 300 mg and 360 mg, and that it had certified to the FDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), that the '791 patent "will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."

Denied that TorPharm's letter failed to provide "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed", as is required by 21 U.S.C. §355(j)(2)(B)(i) and (ii), and that it alleged only in conclusory terms that its proposed ANDA product would not infringe the '791 patent. TorPharm's letter set out a detailed factual and legal basis in support of its certification. Denied in all other respects.

12. Admitted.

13. Denied.

**Count 1 - Infringement Of The '791 Patent  
Under 35 U.S.C. §271(e)(2)**

14. TorPharm incorporates its responses to paragraphs 1-13 herein.

15. Denied.

**COUNT II - Infringement of the '505 Patent  
Under 28 U.S.C. §2201 and 35 U.S.C. §271(a)**

16. TorPharm incorporates its responses to paragraphs 1-13 herein.

17. This is a conclusion of law to which no response is necessary. Subject to the foregoing, TorPharm submits that Biovail has no right under the Declaratory Judgment Act to seek a ruling with respect to the '505 patent as that patent is not listed in the Orange Book as mandated by 21 CFR §314.53(b). The Orange Book requires that an NDA holder/applicant list all relevant patents for which a reasonable claim of patent infringement could be brought if a generic company such as TorPharm manufactured the product.

18. Denied.

19. Denied.

20. Denied.

21. Denied.

22. Denied except admitted that TorPharm's counsel did not provide a copy of TorPharm's ANDA when TorPharm's counsel learned that Biovail breached their agreement for production of the ANDA. Biovail originally requested the ANDA to determine issues of potential infringement of the '791 patent and never informed TorPharm's counsel of the '505 patent. Biovail had only requested the ANDA with respect to determining issues of potential infringement related to the '791 patent which is listed in the Orange Book and for which TorPharm made a paragraph IV patent certification. The '505 patent is not listed in the Orange Book. Thus, Biovail's counsel improperly attempted to obtain TorPharm's ANDA for purposes beyond the '791 patent without any notice to TorPharm's counsel in violation of the parties' agreement and in contempt of the Protective Order entered in a parallel case in the Northern District of Illinois.

23. Denied.

**COUNT III - Infringement of the '505 Patent Under 35 U.S.C. §271(e)(2)**

24. TorPharm incorporates its responses to paragraphs 1-23 herein.

25. Denied.

**AFFIRMATIVE DEFENSES**

- A. The '791 and '505 patents are not infringed.
- B. Plaintiff has failed to state a claim upon which relief may be granted.
- C. The Court lacks jurisdiction to decide issues related to the '505 patent as the '505 patent is not listed in the Orange Book.

- D. Defendant reserves the right to assert further affirmative defenses and counterclaims, including but not limited to invalidity of the patents in suit, unenforceability of the patents in suit, and for anti-trust violations for the institution of a sham suit.

WHEREFORE, Defendant requests that this Honorable Court:

- a. Deny Plaintiff all requested relief and dismiss the Amended Complaint with prejudice.
- b. Order that the effective date of the approval of Defendant's application (ANDA) is immediate under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), upon a statement by the FDA that it is otherwise ready to approve the ANDA.
- c. Declare that the '791 and '505 patents are not infringed.
- d. Defendant further requests that this Court award it its attorneys' fees, costs and all other relief this Court deems just.

#### **COUNTERCLAIMS**

1. Defendant, Counterclaim-Plaintiff, incorporates by reference herein its Answer and Affirmative Defenses to the Amended Complaint.

#### **THE PARTIES**

2. Counterclaim-Plaintiff TorPharm Inc., is a Canadian corporation having a place of business at 50 Steinway Blvd., Toronto, Ontario, M9W 6Y3, Canada. TorPharm is engaged in the business of manufacturing, marketing

and filing for regulatory approvals of generic versions of pharmaceuticals to enable low cost alternative pharmaceuticals to be provided to consumers.

3. On information and belief, Counterclaim-Defendant Biovail Laboratories, Inc. ("Biovail") is a corporation organized and existing under the laws of Barbados and has a place of business in Carolina, Puerto Rico.
4. On information and belief, Biovail is the owner of the '791 and '505 patents.

#### **JURISDICTION AND VENUE**

5. These counterclaims constitute an action for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202, and arise under the Patent Laws of the United States, Title 35, United States Code.
6. This Court has jurisdiction of these counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and Patent Laws of the United States, Title 35, United States Code.
7. In the Complaint, Counterclaim-Defendant alleges that it is the owner of the '791 and '505 patents and allege that Counterclaim-Plaintiff has infringed the '791 and '505 patents.
8. The '791 patent is listed in the Orange Book pursuant to 21 CFR § 314.53(b).
9. TorPharm made a paragraph IV certification to the '791 patent as part of TorPharm's ANDA submission.
10. The '505 patent is not listed in the Orange Book.

11. Since the '505 patent is not listed in the Orange Book, TorPharm was not required to make any certification to the '505 patent as part of its ANDA submission.
12. Under the Food, Drug and Cosmetic Act ("the FDCA"), the Food and Drug Administration ("the FDA") is responsible for determining whether a generic version of a drug product is safe and effective and should be approved for sale to the public under 21 U.S.C. § 355(a) by a generic manufacturer such as Torpharm.
13. Under the Hatch-Waxman Act, a generic pharmaceutical manufacturer such as Torpharm seeking FDA approval to market a generic version of a patented drug such as Diltiazem HCl Capsules Type TZ may submit an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355 (j), also known as Section 505(j) of the FDCA.
14. Torpharm has submitted an ANDA seeking FDA approval to market generic Diltiazem HCl Capsules Type TZ as Plaintiff admitted in its Amended Complaint.
15. Under 21 U.S.C. § 355(j)(6)(A)(i), the Secretary of Health and Human Services (HHS) shall publish and make available to the public a list in alphabetical order of each drug which has been approved for safety and effectiveness (known as the Approved Drug Products With Therapeutic Equivalence Evaluation, also known as the "Orange Book").
16. Diltiazem Hydrochloride is listed in the Orange Book.

17. The Secretary is required to update the list every thirty days under 21 U.S.C. § 355(j)(6)(A)(ii).
18. When an innovators such as the Plaintiff receives a patent covering a pharmaceutical composition or method of using the pharmaceutical composition, the innovator is required to send that information to the Secretary of Health and Human Services so that the patent may be listed in the Orange Book.
19. Thus, when a generic manufacturer such as Torpharm is interested in marketing a generic drug, it would look to the Orange Book for the listed patent information, to determine: which if any patents exist on a particular pharmaceutical product; when those patents expire; whether the proposed product would infringe any of the listed patents; or whether the listed may be invalid.
20. Under 21 U.S.C. § 355(j)(6)(A)(iii), when patent information (e.g., patent number, for each drug for which a reasonable claim of patent infringement could be made) is submitted concerning a drug on the list to be published by the Secretary, the Secretary shall include such information in the Orange Book.
21. Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), found in 21 C.F.R. § 314.94(a)(1-2)(vi), as interpreted by the FDA, an entity submitting an ANDA for a generic product (such as Torpharm) must make a certification to the FDA only for patents listed in the Orange Book.



22. Thus, Torpharm and other generic manufacturers rely and have relied upon the patents listed in the Orange Book in considering whether to file and in filing ANDAs.
23. A patent innovator must list in the Orange Book, drug substance patents (ingredient), drug product patents (formulation and composition) and method of use patents. Process of making the product may not be submitted to the FDA. 21 CFR 314.53(b).
24. When an applicant such as Torpharm submits an ANDA to the FDA, the applicant must certify one of four things under 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (also known as Section 505(j)(2)(A) of the FDCA):
  - (I) that such patent information has not been filed by the patentee (also known as a "paragraph I Certification"); or
  - (II) that such patent has expired (also known as a "paragraph II Certification"); or
  - (III) the date on which the patent will expire (also known as a "paragraph III Certification"); or
  - (IV) that such patent is invalid or that it will not be infringed by the manufacture, use or sale of the new drug for which the ANDA is submitted (also known as a "paragraph IV Certification").
25. Inclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement under the laws of the United States. 35 U.S.C.A. § 271(e)(2)(A).

26. Regarding an ANDA containing a paragraph IV certification, the statute states, "It shall be an act of infringement" to submit an application under 21 U.S.C. § 355(j) "for a drug claimed in a patent ... if the purposes of such submission is to obtain approval ... to engage in the commercial manufacture, use, or sale of [the] drug ... before the expiration of [the] patent."
27. If an ANDA contains a paragraph I or a paragraph II certification as defined above, and all applicable scientific and regulatory requirements have been met, FDA approval of the ANDA is effective immediately under 21 U.S.C. § 355(j)(4)(A), (B)(i).
28. If an ANDA contains a paragraph III certification as defined in ¶18(III) above, and all applicable scientific and regulatory requirements have been met, approval is effective on the patent expiration date stated in the certification under 21 U.S.C. § 355(j)(4)(A), (B)(iv).
29. Under 21 U.S.C. § 355(j)(4)(B)(iii), if the ANDA contains a paragraph IV certification as defined above, and all applicable scientific and regulatory requirements have been met, approval of the ANDA "shall be made effective immediately" unless the patent owner brings an action for infringement under 35 U.S.C.A. § 271(e)(2)(A) within forty-five (45) days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B).
30. The Hatch-Waxman Act further provides that, when a patent owner brings a section 271(e)(2)(A) infringement action, the FDA must suspend approval

of the ANDA for a maximum of thirty (30) months, or until the court rules, whichever is earlier as explained below.

31. Under 21 U.S.C. § 355(j)(4)(B)(iii)(I)-(III), 35 U.S.C. § 271(e)(4)(A), the suspension continues, and the FDA cannot approve the ANDA, until the earliest of three dates:

- (i) if before the expiration of the thirty month period, the court decides that the patent is invalid or not infringed, the date of the court's decision;
- (ii) if before the expiration of the thirty month period, the court decides that the patent has been infringed, the date that the patent expires; or
- (iii) if before the expiration of the thirty month period, the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug, until the court decides that such patent is invalid or not infringed, the date of the court decision.

32. The manufacture, use, or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA. 35 U.S.C. § 271(e)(1).

33. The Hatch-Waxman Act provides under 35 U.S.C. § 271(e)(1), generally that "[i]t shall not be an act of infringement to make, use, or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

34. As evidenced by the Complaint and this pleading in response thereto, Plaintiff submits that there is an actual controversy exists between the parties with respect to the alleged infringement of the '791 and '505 patents.

**COUNT I**

35. Counterclaim-Defendant incorporates by reference herein, paragraph 1-34 of its counterclaims.
36. The '791 patent is not infringed.

**COUNT II**

37. Counterclaim-Defendant incorporates by reference herein, paragraph 1-36 of its counterclaims.
38. The '505 patent is not infringed.

**COUNT III**

39. Plaintiff has failed to state a claim upon which relief may be granted concerning the '505 patent since the '505 patent is not listed in the Orange Book and TorPharm has not provided any patent certification with respect to the '505 patent.
40. The fact that '505 patent is not listed in the Orange Book clearly indicates that Biovail does not have any "reasonable belief" as required by the statute that the manufacture of TorPharm's proposed product would infringe the '505 patent.
41. Biovail's claim is an attempt to unduly delay this case and maintain its monopoly power in the marketplace for the product.

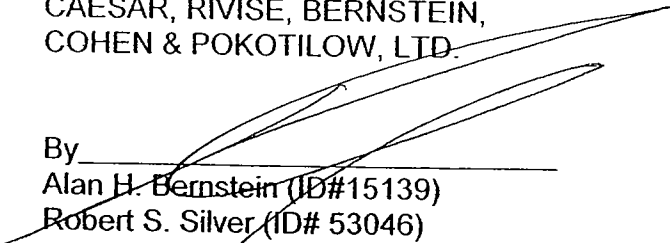
PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff requests that this Honorable Court:

- a. Deny Counterclaim-Defendant all requested relief and dismiss the Amended Complaint with prejudice.
- b. Adjudge and decree that the '791 and '505 patents are not infringed.
- c. Order that the effective date of the approval of TorPharm's Abbreviated New Drug Application (ANDA) is immediate under § 505(j) of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), and its use, upon a statement by the FDA that it is otherwise ready to approve the ANDA.
- d. Counterclaim-Plaintiff further requests that this Court award it its attorneys' fees, interests and costs.
- e. Counterclaim-Plaintiff requests that it be granted such other and further relief as this Court deems just and proper.

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

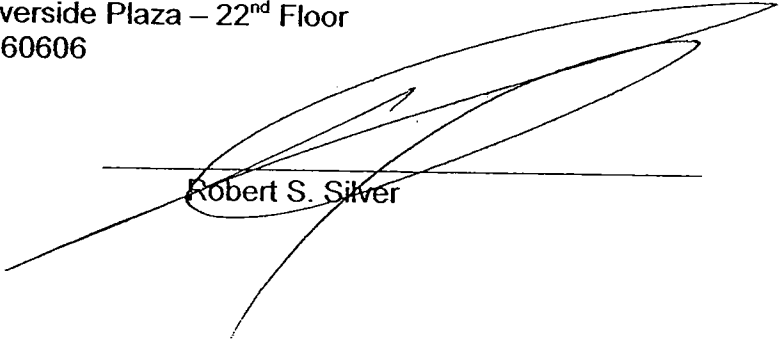
October 10, 2002

By   
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215-567-2010

CERTIFICATE OF SERVICE

A copy of the foregoing was served on October 10, 2002, by postage prepaid, first class mail, via the United States Postal Services in an envelope addressed to the the following counsel:

Eric C. Cohen  
WELSH & KATZ, LTD.  
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Chicago, IL 60606



Robert S. Silver